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Statement before the TSE Advisory Committee on January 17, 2002 vCJD Deferral Policies

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America's Blood Centers (ABC) is a national network of locally-controlled, non-profit community blood centers that collect half of the US blood supply from volunteer donors. Collectively, we operate in 45 states and serve more than half of the nation's 6,000 hospitals. America's Blood Centers' total blood collections exceeded 6.7 million pints in the year 2000.

ABC members thank FDA for incorporating some of our comments into the newly published Final Guidance. However, some important issues remain unresolved. One, we are concerned about the impact of the donor questions. We hope that FDA will take into account the studies and proposals being made by the Donor History Task Force of the American Association of Blood Banks. We also hope that the Task Force recommendations will be considered in a speedy manner. While there is opportunity for change through submissions requesting permission for the use of alternative procedures, these concessions, if granted, are not granted quickly. A community that is driven by regulatory compliance and appreciates the importance of prompt implementation of new guidelines will find it easier to follow the rules than to change them.

The other open issue is the actual impact that implementation will have on the blood supply. When this Committee met last October, we were still in the height of the public response to the September 11 terrorist attacks. Blood bank refrigerators were full, we had two weeks of supply, and it was difficult for the public and even for some blood bankers to envision future shortages. However, the donors' enthusiasm predictably waned, and we now are back into a very severe post-holiday shortage situation. We believe that these shortages are being aggravated by the implementation of unjustifiably stringent deferrals by the American Red Cross, affecting about half of the blood collections in the US.

I want to reemphasize the position of ABC member centers regarding vCJD deferrals. They strongly believe that FDA made an enlightened decision in its approach to balance blood safety and availability. All but one of ABC's 74 member centers based in the United States plan to implement the FDA recommendations as recommended in the Final Guidance. Over 99% of the almost 7 million collections made by ABC member centers will be performed according to the FDA-recommended criteria.

ABC members want to reaffirm their support of FDA as the agency responsible for setting national blood safety guidelines. We strongly disagree with the more restrictive approach implemented by the American Red Cross because it may reduce the donor base by 8-9% without the benefit of additional protection. Both the FDA algorithm and the ARC algorithm achieve statistically identical protection from theoretical risk. The difference—and it is an important difference—is in the donor loss.

ABC member centers have embarked on an aggressive donor recruitment effort that we call the Member Donation Initiative, or MDI. We have engaged a marketing consulting firm, performed extensive research on donor behavior, and developed an advertising campaign that is now being launched by the majority of the centers. We have also been placing substantial effort to the recruitment of individuals who donated or attempted to donate in the days following the September 11 terrorist attack. Our success has been at most modest. Our research, plus the experience of past events such as the Gulf War and the Oklahoma bombing suggest that most of these individuals promptly respond to national emergencies, but rarely become regular blood donors. We are optimistic about MDI, and expect that our substantial financial investment will go a long way to help compensate for the expected donor loss caused by the vCJD deferrals.

We also believe that blood availability must be monitored, in order to assess the health of the US blood system. We applaud HHS in its efforts to monitor the blood supply in hospitals and transfusion services. In order to complement this effort, we have implemented a system for monitoring the supply of ABC member centers. We call it "The Stoplight". Every morning, through an automated e-mail system, members report the status of their inventory: green, for a three day supply or more, yellow for a two day supply, and red for one day supply or less. The results are compiled automatically and aggregate results, calculated for regions of the country that match those of the HHS survey, are posted on our web site. The system is being tested internally, and the data will become public in the next few weeks. Essentially, the public, the healthcare system and the regulators will have a daily picture of the status of the blood supply among ABC member centers by simply logging into the ABC website. It is important that we monitor the impact of the vCJD deferrals, and take action to change them if the system cannot tolerate the donor loss without affecting healthcare.

Finally, we commend FDA and this Committee in their efforts to correlate vCJD deferrals with the implementation of national policies on food controls. Let's not forget that the recommended pan-European deferral is additive. Donors who donate next November may take one more winter trip to Europe that prevents them from donating in the following February and ever after. It is critical to increase the specificity of the deferrals by limiting them to the actual periods during which the theoretical risk is the highest.

We ask that this committee continue to evaluate the potential for transmissibility of vCJD by blood transfusion. We are encouraged by the lack of evidence of transmission as the observation period is extended, and by the recently published studies predicting that the number of cases of human vCJD will be small. We are also encouraged by efforts being applied in the development of tests for the detection of prions in humans. We hope that epidemiology and screening tests will help us eliminate geographical deferrals with limited specificity in the foreseeable future.

Thank you very much for the opportunity to present our point of view.